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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/862,690 | 05/22/2001 | Robert John Cottone, JR. | 1133279-0004 | 8698 |

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WHITE & CASE LLP
PATENT DEPARTMENT
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NEW YORK, NY 10036

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| EXAMINER |
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WEBB, SARAH K

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,690

Applicant(s)

COTTONE, ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4,6,7,14-18, 24-27, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,824,043 (Cottone, Jr.).

Cottone discloses a stent (21) in Figures 1 and 3 that includes a continuous first helix (14) that proceeds in a first direction circumferentially along the tube. The first helix has a plurality of undulations formed by ascending and descending arms (16) connected at a junction point (17). The undulations can be described as having either a "sinusoidal" pattern or a "zigzag" pattern. Connection elements (18) connect adjacent undulations to form a second helix that proceeds in a second direction (A). The term "connection element" is sufficiently broad to encompass a structure that connects two elements together. Therefore, the welds (18) of Cottone meet this limitation. There are at least two connection elements (18) in each 360-degree turn of the first helix. The stent does not have any free ends, as the ends of the first helix (14) are connected to the previous turns of the helix and closed by connection elements (18). This is clearly illustrated in Figures 3 and 4. Cottone explains that the stent can be made of a nickel-titanium alloy (column 8, line 25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5, 19, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottone in view of US Patent No. 5,843,175 to Frantzen.

Cottone includes all the limitations of claims 5, 19, and 33, but fails to form the stent so that there are four connection elements per 360-degree turn of the first helix. Frantzen teaches that a stent can have four connection elements per every 360 turn, as shown in Figure 16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have four connection elements per every 360 turn of the first helix of Cottone, as taught by Frantzen, as this is simply a modification in the number of components.

3. Claims 8, 9, 20, 21, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottone in view of WO 97/21399 (Haffner).

The first helix of Cottone terminates in a "transition zone" where the end of the first helix is connected back to the previous turn of the helix to form a closed loop. The amplitude of the undulations in this "transition zone", or final turn of the helix, does not increase as the undulations proceed towards the closing point of the loop. Haffner illustrates in Figure 1 that the undulations in the final turn of a continuous helix can

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increase towards the end of the turn. This increase is clearly illustrated in segments "a" and "e" in Figure 1. It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the amplitude of the undulations in the transition zones of Cottone, as Haffner teaches by illustration that this is simply another way to form the final turn of a helical stent.

4. Claims 10-13, 22, 23, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottone, as modified by Haffner above, and in further view of US Patent No. 6,315,794 (Richter).

Cottone, as modified by Haffner above, fails to include a closed circumferential element that is linked to the transition zone by connection elements. Haffner does illustrate in Figure 3 that a helical stent (12) can have closed circumferential elements (5 and 9) linked to either end of the helix by connection elements (10). Richter discloses a stent in Figure 3A that is formed similar to Cottone and Haffner in that there are adjacent undulations of 360 turns linked by connection elements. Richter illustrates that this type of stent can include closed circumferential elements (11,112) linked to the ends of the main structure by connection elements. Richter teaches that the closed circumferential elements (111,112) on either end of the stent should be radiopaque, because this type of marking is useful for accurate positioning of the ends of the stent in critical circumstances (column 4, lines 50-65). Richter goes on to state that the elements (11,112) are formed of suitable radiopaque materials, such as gold and silver. It would have been obvious to one of ordinary skill in the art at the time the invention

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was made to include radiopaque closed circumferential elements linked by a plurality of connection elements to the transition zone of Cottone's stent, as modified by Haffner, in order to provide greater accuracy in positioning of the stent.

Response to Arguments

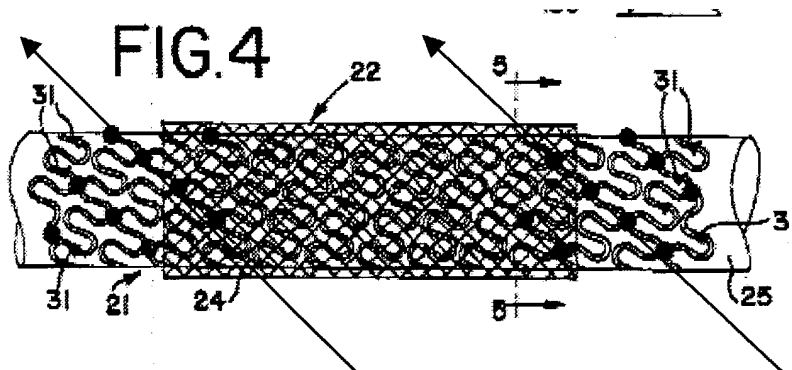
5. Applicant's arguments filed 10/27/04 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., separate connection elements like the ones shown in Figure 2 and 13 of the specification; the second helix runs along the length of the stent, squared off ends) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claim language is very broad, so many structures different from the illustrations read on the claims. Applicant uses the broad term "connection elements" in the claims, which is sufficiently broad to encompass any structure that connects two elements together.

Applicant argues that the second helix does not run along the length of the stent. Since it is neither disclosed in the specification nor stated in the claims, the second continuous helix is not required to run along the length of the stent. Rather, it is shown that the second helices (39 and 40 in Figures 4 and 15) run along only a portion of the length of the stent.

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6. Applicant argues that Cottone does not include a second continuous helical element. Applicant discloses in the specification that a "second continuous helix" is made up of segments of the first undulating helix and connection elements (see Figure 15). Each second helix (39,40) in Figure 15 does not extend the length of the stent. As shown below, Cottone also includes connection elements that connect segments of adjacent turns of the first helix to form a "second continuous helix." Therefore, this structure reads on the claims. The following figure more clearly identifies the "second continuous helix" of Cottone by arrowed lines:



Further, there are clearly many undulations of adjacent turns that are not connected, which are indicated by undulations that do not have black dot (weld).

7. Applicant argues that Cottone does not have true "junction points." Applicant states that a junction point as defined by the specification is a location where *ascending and descending arms of a zigzag element are joined to ascending and descending arms of a zigzag element in an adjacent turn by a connection element*. Cottone clearly includes such a junction point. As clearly illustrated above, the connection elements (18) of Cottone join ascending and descending arms of one zigzag element to ascending and descending arms of an adjacent zigzag element.

Conclusion

8. This is a continuation of Application No. 09/862,690. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhthuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW

11/19/04

SKW

Julian W. Woo

**JULIAN W. WOO
PRIMARY EXAMINER**